

(19)



Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) **EP 1 417 963 A1**

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:

12.05.2004 Bulletin 2004/20

(21) Application number: 03079169.3

(22) Date of filing: 21.01.2000

(51) Int Cl.7: **A61K 31/23**, A61P 25/18,
A61K 31/40, A61K 31/445,
A61K 31/495, A61K 31/505,
A61K 31/54, A61K 31/55,
A61K 31/202

(84) Designated Contracting States:

AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE

Designated Extension States:

AL LT LV MK RO SI

(30) Priority: 27.01.1999 GB 9901809

(62) Document number(s) of the earlier application(s) in
accordance with Art. 76 EPC:
00900733.7 / 1 148 873

(71) Applicant: **Laxdale Limited**
Stirling FK7 9JQ (GB)

(72) Inventors:

- **Peet, Malcolm**
Sheffield S10 2QQ (GB)
- **Vaddadi, Krishnarao Sitamrao**
Melbourne 3106 (AU)

(74) Representative: **Wakerley, Helen Rachael**

Reddie & Grose,
16 Theobalds Road
London WC1X 8PL (GB)

Remarks:

This application was filed on 23 - 12 - 2003 as a
divisional application to the application mentioned
under INID code 62.

(54) **Highly purified EPA and derivatives for psychiatric and neurological disorders**

(57) A pharmaceutical preparation comprising EPA in an appropriately assimilable form where of all the fatty acids present in the preparation at least 90%, and preferably at least 95%, is in the form of EPA and where less than 5%, and preferably less than 3%, is in the form of DHA is provided for the treatment of a psychiatric or cen-

tral nervous disorder. The preparation may be administered with conventional drugs to treat psychiatric or central nervous disorders including anxiety, sleep disorder, attention deficit, hyperactivity, schizophrenia, depression, Alzheimer's disease, Parkinson's disease, etc.

EP 1 417 963 A1

- nervous system disorder of a preparation comprising EPA in an appropriately assimilable form where of all the fatty acids present in the preparation at least 95% is in the form of EPA, and where less than 3% is in the form of docosahexaenoic acid (DHA).
3. Use according to claim 2 for the manufacture of a medicament for the treatment of schizophrenia, schizoaffective disorder or schizotypal disorder.
 4. Use according to claim 2 for the manufacture of a medicament for the treatment of depression.
 5. Use according to claim 2 for the manufacture of a medicament for the treatment of Alzheimer's disease or another dementia, including multi-infarct dementia, Lewy body disease and diseases attributable to prion disorders.
 6. Use according to claim 2 for the manufacture of a medicament for the treatment of Parkinson's disease, or other motor system disorder.
 7. Use according to any preceding claim in which the EPA is in the form of ethyl-EPA, lithium EPA, mono-, di- or triglyceride EPA or any other ester or salt of EPA, or the free acid form of EPA, or other appropriate bioavailable derivative which raises EPA levels within the body.
 8. Use according to any preceding claim in which the EPA is in the form of a 2-substituted derivative or other derivative which reduces the rate of oxidation without impairing its biological activity.
 9. Use according to any preceding claim in which the preparation further comprises a drug which acts primarily on the neurotransmitter metabolism or receptors.
 10. Use according to claim 9 in which the drug is clozapine.
 11. Use according to claim 9 in which the drug is any one of the class of typical or atypical neuroleptics, including chlorpromazine, haloperidol, risperidone, olanzapine, sertindole, ziprasidone, zotepine or amisulpride.
 12. Formulations for use in psychiatric and neurological disorders in which a drug selected from clozapine and any one of the class of typical or atypical neuroleptics, including chlorpromazine, haloperidol, risperidone, olanzapine, sertindole, ziprasidone, zotepine or amisulpride is prepared for co-administration with a pharmaceutical preparation comprising EPA in an appropriately assimilable form where of all the fatty acids present in the preparation at least 95% is in the form of EPA, and where less than 3% is in the form of docosahexaenoic acid (DHA).
 13. A pharmaceutical formulation comprising: a preparation comprising EPA in an appropriately assimilable form where of all the fatty acids present in the preparation at least 95% is in the form of EPA, and where less than 3% is in the form of docosahexaenoic acid (DHA); together with a drug selected from clozapine and any one of the class of typical or atypical neuroleptics, including chlorpromazine, haloperidol, risperidone, olanzapine, sertindole, ziprasidone, zotepine or amisulpride.
 14. A formulation according to claim 12 or 13 in which the EPA is in the form of ethyl-EPA, lithium EPA, mono-, di- or triglyceride EPA or any other ester or salt of EPA, or the free acid form of EPA, or other appropriate bioavailable derivative which raises EPA levels within the body.
 15. A formulation according to any of claims 12 - 14 in which the EPA is in the form of a 2-substituted derivative or other derivative which reduces the rate of oxidation without impairing its biological activity.